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CHAIRMAN BUYER'S OPENING REMARKS MILITARY PERSONNEL SUBCOMMITTEE HEARING ON DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM

Good morning. This hearing of the Subcommittee on Personnel of the House of Representatives Committee on Armed Services will come to order.

This is the second hearing the subcommittee has held on the Department of Defense Anthrax Vaccine Immunization Program.

Earlier this week, in response to growing problems with the potency testing of the anthrax vaccine, the Secretary of Defense announced a temporary slow-down in this important element of the Department's force protection strategy. The witnesses appearing before the subcommittee today will provide testimony on the overall program and the Department's approach to managing the dwindling supply of vaccine in the face of a continuing threat. We will also receive testimony about the vaccine manufacturer, BioPort Corporation's, efforts to gain FDA approval of their new manufacturing facility and their contractual relationship with the Department of Defense.

I am, as always; glad to be joined in these efforts by the ranking member, Mr. Abercrombie as we oversee in a non-partisan way, the Department of Defense efforts to protect the men and women of the Armed Forces from this particular threat. I am also pleased to welcome to the dais today our colleague from the full committee, Mr. Jones and also Mr. Shays from the Committee on Government Reform. Both of these gentlemen have been heavily engaged in the oversight of this program from its beginning.

The House of Representatives Committee on Armed Services has closely followed the Department's implementation of AVIP since its inception. As chairman of the personnel subcommittee, a Gulf War veteran who has personally experienced some of the symptoms of Gulf War illnesses, and a recipient of the anthrax vaccine, I am keeping particularly close tabs on this program.

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The driving force for this program is the threat of exposure to weaponized anthrax. Absent the threat, the vaccination program would be unnecessary. However, absent the vaccination in the presence of a known threat, unprotected exposure would result in near certain death. The central questions we on the committee must continue to ask are: (1) how real is the threat; (2) is the vaccine safe and (3) is the vaccine reliably effective against the threat.

I remain convinced that the threat is real and that the Department of Defense is obligated – indeed has a clear duty — to take all necessary actions to protect our soldiers, sailors, airmen and marines against this deadly biological weapon. On the issue of safety, I believe the Department has responded to our concerns by increasing its monitoring efforts and working with the Food and Drug Administration, aggressively reviewing the vaccine adverse event reports that service members are encouraged to submit if they have a reaction to the shots. That brings us to the potency of the vaccine and the tests that each lot of the vaccine must satisfactorily complete prior to release for use by the force. Several of the most recent potency tests have resulted in multiple lots of the vaccine, all of which were previously approved for safety and purity, not being approved for use because they failed the tests for potency. In other words, the vaccine in those lots was not proven in accordance with FDA standards to be effective in protecting against anthrax used as a weapon. These failures combined with the inability of Bioport to produce vaccine in the renovated production facility have resulted in the Department of Defense actions taken earlier this week to temporarily slow-down the rate at which the force is administered the anthrax vaccine.

Among our witnesses today is a representative from the Food and Drug Administration. In my view the FDA's tough standards have been critical to maintaining support for this program. The FDA managers have insisted on the toughest standards before authorizing the release of already manufactured anthrax vaccine or approving the new production facility. Their continued rigorous oversight will be critical to continuation of the program.

Clearly the current strategy did not anticipate problems with the potency testing of the vaccine or that it would take so long to achieve final approval for new production of vaccine. This unexpected delay combined with a limited supply of vaccine and new problems with pre-release potency tests have resulted in the Secretary of Defense's decision to slow the program until guaranteed production can be assured.

From the outset of this program my support has been based on three considerations. First, the threat is real. Second, the vaccine used to protect against the threat is safe and, third, the vaccine is effective. The last lots of vaccine subjected to the potency tests have not passed. This at least raises some reasonable doubts as to the effectiveness of these lots of vaccine for actually protecting the force. Problems with potency testing of the current inventory of vaccine makes achieving full production of new vaccine in the renovated facility crucial to continuing this program.

I continue to be convinced that our soldiers, sailors, airmen and marines are better protected with a safe and potent anthrax vaccine than they would be without it. However, I am concerned about the Department of Defense's short, intermediate and long-term strategies for providing that protection and I look forward to hearing their testimony on those challenges.

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